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Sarwat Khattak, and Greg Randall

Serial No.: 10/053,929 Art Unit: Not Yet Assigned

Filed: January 22, 2002 Examiner: Not Yet Assigned

For: *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

Assistant Commissioner for Patents  
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT

Sir:

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Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twelve (12) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/433,486, filed November 4, 1999, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: 10/053,929

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**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Dated: June 12, 2002

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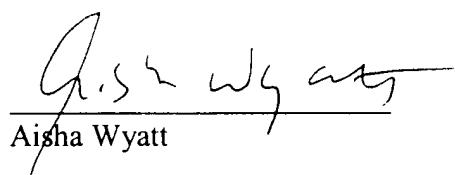
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/053,929
(Use as many sheets as necessary)		Filing Date	January 22, 2002
		First Named Inventor	Julie Straub
		Group Art Unit	
		Examiner Name	
Sheet	of	12	Attorney Docket Number
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Sheet 2 of 12

Application Number	10/053,929 JUN 27 2002
Filing Date	January 22, 2002
First Named Inventor	Julie Straub
Group Art Unit	
Examiner Name	
Attorney Docket Number	ACU 109 CIP

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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,591,456		Franson, et al.	01-07-1997	
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		WO	98/31346	A1	Massachusetts Institute of Technology	07-23-1998
		WO	98/51282	A1	Imaxx Pharmaceutical Corp.	11-19-1998

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		ADEYEYE & PRICE, "Chemical, dissolution stability and microscopic evaluation of suspensions of ibuprofen and sustained release ibuprofen-wax microspheres," <i>J. Microencapsul.</i> 14(3):357-77 (1997).
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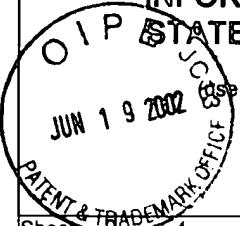
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		First Named Inventor	TECH CENTER 1600/2000 Julie Straub
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		BADIGER, et al., "Porogens in the preparation of microporous hydrogels based on poly(ethylene oxides)," <i>Biomaterials</i> 14:1059-63 (1993).	
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		CHIOU & RIEGELMAN, "Pharmaceutical applications of solid dispersion systems," <i>J. Pharm. Sci.</i> 60:1281-1302 (1971).	

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		First Named Inventor	Julie Straub
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		CHIOU, et al., "Enhancement of dissolution rates of poorly water-soluble drugs by crystallization in aqueous surfactant solutions I: Sulfathiazole, Prednisone, and Chloramphenicol," <i>J. Pharm. Sci.</i> 65:1702-04 (1976).	
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		FORD, "The current status of solid dispersions," <i>Pharm. Act. Helv.</i> 61:69-88 (1986).	
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		HIRSCHBERG, et al., "Oral absorption of CGS-20625, an insoluble drug, in dogs and man," <i>J. Pharmacokinet. Biopharm.</i> 23(1):11-23 (1995).	
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		KHAN & JIABI, "Preparation, characterization, and dissolution studies of ibuprofen solid dispersions using polyethylene glycol (PEG), talc, and PEG-talc as dispersion carriers," <i>Drug Dev. Ind. Pharm.</i> 24(5):455-62 (1998).	
		KHAN, et al., "Controlled release coprecipitates: formulation considerations," <i>J. Control. Rel.</i> 37:131-41 (1995)	
		KIM & YOON, "Development of digoxin dry elixir as a novel dosage form using a spray-drying technique," <i>J. Microencapsul.</i> 12(5):547-56 (1995).	
		KINCL, et al., "Increasing oral bioavailability of progesterone by formulation," <i>J. Steroid. Biochem.</i> 9(1):83-84 (1978).	
		KONDO, et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol. Pharm. Bull.</i> 16(8):796-800 (1993).	
		KUBO & MIZOBE, "Improvement of dissolution rate and oral bioavailability of a sparingly water-soluble drug, (+/-)-5-[[2-(2-naphthalenylmethyl)-5-benzoxazolyl]-methyl]- 2, 4-thiazolidinedione, in co-ground mixture with D-mannitol," <i>Biol. Pharm. Bull.</i> 20(4):460-63 (1997).	
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		LEMOS-SENNNA, et al., "Evaluation of the hydrophobic drug loading characteristics in nanoprecipitated amphiphilic cyclodextrin nanospheres," <i>Pharm. Dev. Tech.</i> 3:85-94 (1998).	
		LEUCUTA, et al., "The kinetics of nifepipine release from porous hydrophilic matrices and the pharmacokinetics in man," <i>Pharmazie</i> 43:845-48 (1988).	

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Sheet	of	12	Application Number	10/053,929	JUN 27 2002
			Filing Date	January 22, 2002	TECH CENTER 1600/2900
			First Named Inventor	Julie Straub	
			Group Art Unit		
			Examiner Name		
			Attorney Docket Number	ACU 109 CIP	

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		LIN, et al., "Improved oral absorption of L-365260, a poorly soluble drug," <i>Biopharm. Drug Dispos.</i> 17(1):1-15 (1996).	
		LIN, et al., "Preparation of enteric-coated microspheres of <i>Mycoplasma hyopneumoniae</i> vaccine with cellulose acetate phthalate: (II). Effect of temperature and pH on the stability and release behaviour of microspheres," <i>J. Microencapsul.</i> 8(4):537-45 (1991).	
		MARTINDALE, <i>The Extra Pharmacopoeia</i> , 711 Dissolution, pp. 1791-92, 30th Ed. (The Pharmaceutical Press, London 1993).	
		MASON & WINER, "Kinetics of aspirin, salicylic acid, and salicyluric acid following oral administration of aspirin as a tablet and two buffered solutions," <i>J. Pharm. Sci.</i> 70(3):262-65 (1981).	
		MIGLIARESI, et al., "Physical characterization of microporous poly(2-hydroxyethyl methacrylate) gels," <i>J. Biomed. Mater. Res.</i> 15:307-17 (1981).	
		MISHRA & YALKOWSKY, "A flat circular hole device for zero-order release of drugs: characterization of the moving dissolution boundary," <i>Pharm. Res.</i> 7(11):1195-97 (1990).	
		MORRIS, et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," <i>J. Pharm. Sci.</i> 81(12):1185-88 (1992).	
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		NYSTRÖM & WESTERBERG, "The use of ordered mixtures for improving the dissolution rate of low solubility compounds," <i>J. Pharm. Pharmacol.</i> 38(3):161-65 (1986).	

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		Filing Date	January 22, 2002
		First Named Inventor	Julie Straub
		Group Art Unit	
		Examiner Name	
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		NYSTRÖM, et al., "Dissolution rate measurements of sparingly soluble compounds with the Coulter Counter model TAII," <i>J. Pharm. Pharmacol.</i> 37(4):217-21 (1985).
		OTSUKA, et al., "Hygroscopic stability and dissolution properties of spray-dried solid dispersions of furosemide with Eudragit," <i>J. Pharm. Sci.</i> 82(1):32-38 (1993).
		PACE, et al., "Novel injectable formulations of insoluble drugs," <i>Pharmaceutical Technology</i> 116-34 (March 1999).
		PILLAY & FASSIHI, "A new method for dissolution studies of lipid-filled capsules employing nifedipine as a model drug," <i>Pharm. Res.</i> 16(2):333-37 (1999).
		REDDY, et al., "Dissolution characteristics and oral absorption of digitoxin and digoxin coprecipitates," <i>J. Pharm. Sci.</i> 65(12):1753-58 (1976).
		RIDOLFO, et al., "Benoxyprofen, a new anti-inflammatory agent: particle-size effect on dissolution rate and oral absorption in humans," <i>J. Pharm. Sci.</i> 68(7):850-52 (1979).
		SAANO, et al., "Relative pharmacokinetics of three oral 400 mg ibuprofen dosage forms in healthy volunteers," <i>Int. J. Clin. Pharm. Ther.</i> 29:381-85 (1991).
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		SERAJUDDIN, et al., "Effect of vehicle amphiphilicity on the dissolution and bioavailability of a poorly water-soluble drug from solid dispersions," <i>J. Pharm. Sci.</i> 77(5):414-17 (1988).
		SERAJUDDIN, et al., "Improved dissolution of a poorly water-soluble drug from solid dispersions in polyethylene glycol: polysorbate 80 mixtures," <i>J. Pharm. Sci.</i> 79(5):463-64 (1990).

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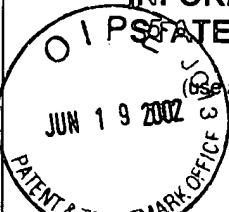
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		First Named Inventor	Julie Straub
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		SERAJUDDIN, et al., "Water migration from soft gelatin capsule shell to fill material and its effect on drug solubility," <i>J. Pharm. Sci.</i> 75(1):62-64 (1986).
		SUZUKI & SUNADA, "Comparison of nicotinamide, ethylurea, and polyethylene glycol as carriers for nifedipine solid dispersion systems," <i>Chem. Pharm. Bull.</i> 45:1688-93 (1997).
		SUZUKI & SUNADA, "Influence of water-soluble polymers on the dissolution of nifedipine solid dispersions with combined carriers," <i>Chem. Pharm. Bull.</i> 46:482-87 (1998).
		SWEETANA & AKERS, "Solubility principles and practices for parenteral drug dosage form development," <i>PDA J. Pharm. Sci. Technol.</i> 50(5):330-42 (1996).
		TAKENAKA, et al., "Preparations of solid particulates of theophylline-ethylenediamine complex by a spray-drying technique," <i>J. Pharm. Sci.</i> 71(8):914-19 (1982).
		TAKEUCHI, et al., "Enhancement of the dissolution rate of a poorly water-soluble drug (tolbutamide) by a spray-drying solvent deposition method and disintegrants," <i>J. Pharm. Pharmacol.</i> 39(10):769-73 (1987).
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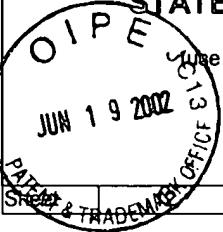
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		VENKATARAM & ROGERS, "Characteristics of drug-phospholipid coprecipitates I: Physical properties and dissolution behavior of griseofulvin-dimyristoylphosphatidylcholine systems," <i>J. Pharm. Sci.</i> 73(6):757-61 (1984).	
		VUDATHALA & ROGERS, "Dissolution of fludrocortisone from phospholipid coprecipitates," <i>J. Pharm. Sci.</i> 81(3):282-86 (1992).	
		WAN, et al., "Plasticizers and their effects on microencapsulation process by spray-drying in an aqueous system," <i>J. Microencapsul.</i> 9(1):53-62 (1992).	
		WESTERBERG, et al., "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures," <i>Int. J. Pharm.</i> 28:23-31 (1986).	
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